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13. ABSTRACT (Maximum 200) A new digital prototype, developed by 3M Imaging Systems based on a novel photo-conductor sensor was installed at Georgetown University for technical and clinical evaluation. The detector system was based on a multilayer structure containing a photo-conductor. The latent image produced by an x-ray was stored on the photo-conductor surface, and was then read out by scanning with a high intensity laser beam. The system was expected to have both a wider dynamic range and good spatial resolution compared to conventional screen-film system. The physical characteristics of the system were studied on phantom images for image quality and radiation dose. The evaluation of the 3M system was divided into two parts: (1) system performance for different kVp and mAs, and (2) system optimization for minimum patient dose. The performance of the system was tested on the body part images that are less radio-sensitive than breast images (i.e., extremities). The system's performance was improved mainly by redesigning the detector structure and using different image processing parameter settings. Comparison of 3M and screen-film images for less radio-dense body parts show that 3M system is not suitable for breast imaging at this time.					
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The Final Report
on
CLINICAL EVALUATION OF A DIGITAL MAMMOGRAPHY
BASED ON MICRO-LITHOGRAPHY

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CLINICAL EVALUATION OF A DIGITAL MAMMOGRAPHY BASED ON MICRO-LITHOGRAPHY

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Principal Investigator: Seong K. Mun, PhD

1. INTRODUCTION

The incidence of breast cancer is increasing. Each year more than 182,000 women will be diagnosed with breast cancer and 46,000 will die of breast cancer in the United States of America.¹ Breast cancer is a major health problem in the U.S. and is the second most frequent cause of cancer death among women after lung cancer.²⁻⁴ Unlike lung cancer, however, the causes of breast cancer have not yet been identified, and until then a formal methodology for preventing and curing breast cancer remains unknown.

The goal of mammography is the reduction of mortality by the detection of breast cancer at the earliest possible stage. X-ray mammography is acknowledged to be the most sensitive and specific technique for detection of breast cancer in its earliest and most curable stages. The NCI-NASA Working Group Digital Mammography Technology Transfer Workshop held in May 1993 identified digital mammography as the most promising novel technology for improving mammographic performance. Despite its status as the method of choice in breast cancer detection, it is clear that significant improvements in mammographic performance are possible. Kopans and Plewes, at the National Cancer Institute Consensus Conference "Breast Imaging; State-of-the-Art and Technologies of the Future," stated that "While there is room for continued development with conventional methods, it is believed that advances in digital acquisition and manipulation of breast images represent the most fertile territory for major advances in the x-ray detection and diagnosis of minimal breast cancers."⁵ While digital technology offers many benefits, its full potential will be realized only when it is carefully integrated into the overall design of mammography systems.

One potential advantage of digital over screen-film mammography is higher detector efficiency, since detectors, in principle at least, are subject to noise limitations such as that associated with film granularity in screen-film mammography. A second advantage of digital mammography is much higher detector dynamic range, which would permit significantly improved recording of information in areas of the image exposed to radiation levels significantly lower or higher than the optimal level. Maidment et al.⁶ estimate that dynamic ranges of well over three orders of magnitude will be produced in digital mammography. Wagner⁷ has shown that if dynamic range is defined by the high and low exposures that correspond to degradation of detector detective quantum efficiency (DQE) to ten percent of its maximal value, the dynamic range of screen-film systems is barely one order of magnitude, rather than the two to three orders of magnitude that might be inferred from considering film only as a display medium. A third major advantage of digital mammography is that it permits consideration of display characteristics independent of the image capture requirements of the system. The recent work of Sabol et al.⁸ on scanning equalization mammography includes a striking demonstration of the combined effects of non-optimal display and limited dynamic range, in a DQE sense, in conventional mammography.

Additional advantages of digital mammography are related to the fact that direct digital acquisition of the image greatly facilitates image processing, computer-aided diagnosis, and image transmission.

Small calcifications are one of the earliest and most reliable, although nonspecific, findings of early and minimally invasive breast cancer.⁹ Detection of such lesions truly tests the ability of the present digital systems compared to the conventional screen-film system which has a far lower spatial resolution.^{10,11} Even digitization of conventional mammographic films with fine pixel size (100 x 100 μm) degrades the detectability of microcalcifications. High quality mammography images require excellent spatial resolution in order to detect fine and subtle microcalcifications within the breast. At the same time excellent contrast sensitivity is needed for seeing the subtle differences in x-ray attenuation coefficient between normal and malignant tissues.¹²

Up to the present time, the only commercially available technology that has been used to perform digital full breast studies is based on the storage phosphor computed radiography (CR) system developed by Fuji. Both digital and screen-film systems have been improved significantly, but the characteristic of the systems (i.e., spatial resolutions and contrast detectability for detection of microcalcifications) remained the same. Technologies which may produce digital detectors with both a higher resolution and a field of view needed for mammography are now in the development stage by many radiographic industries. 3M Corporation has offered Georgetown University their new technology which we expect to have significant advantages over the existing conventional and digital technologies. This new system is expected to have both a wider dynamic range and a higher spatial resolution than the conventional screen-film and Fuji CR system.

The new digital system developed by 3M^{13,14}, uses a detector system based on a multilayer structure containing a photo-conductor. The latent image produced at the photo-conductor surface is then read out by scanning the plate with a laser beam. After the laser read out, the image will be processed digitally. The resulting image will be processed and viewed as a soft copy display or a hard copy film as needed. The prototype device operates with a wide dynamic range and produces linear x-ray signal response for clinically reasonable x-ray exposure. Clinical image quality can be obtained at x-ray exposures that are comparable to those used in a conventional screen-film system.

Before conducting the clinical study in a mammography energy range, the system was evaluated for imaging body parts which are less radio-sensitive than breast images. First, phantom study was performed on extremities, the hip, and the shoulder. The physical characteristics of the system such as image quality and radiation dose were studied. In that evaluation the radiation dose was optimized for extremities and the system was improved significantly, mainly by redesigning the detector and using image processing to enhance the contrast and spatial frequency for better image quality. The phantom study's evaluation was divided into two parts. In the first part, the performance of the system was evaluated in high kVp on the study of extremities, hip and shoulder. In the second part, system optimization was performed in order to minimize the patient dose on the extremities. Then in the second study, a very limited patient study was performed for extremities to conclude that if the new system is ready for clinical study in mammography.

2.0 METHODS

The 3M imaging system is a new technology that has not yet been established as suitable for clinical mammography examination. Therefore, a sequence of experiments was performed to study the system's physical characteristics, image quality, and image sensitivity. The study also includes radiation dose optimization for good image quality. The experiments were performed on body parts that are less radio-sensitive than the breast. The physical characteristics of the system such as image quality and radiation dose were studied in an energy range higher than mammography energy range. The study was performed in three years:

Year 1

The first year we concentrated on the initial tests of the 3M system on the extremities phantoms for a range of kVp and mAs. The results showed that the machine did not have sufficient image quality to proceed with a clinical trial in mammography energy range (Reference to the Report on the First Year Project).

Year 2

Image optimization was performed on body parts that are less radio-dense than the breast. Several major adjustments were made to improve the image quality of the system. The system was improved mainly by redesigning the detector structure and using image processing parameter settings. By the completion of the second year, the radiation exposure was optimized and the image quality was improved. The study concentrated on the extremities, hip, and shoulder phantoms (Reference to the Report on the Second Year Project).

Year 3

In the final year, we have concentrated on thin and medium size anatomy such as hand, foot, ankle, elbow, knee, and shoulder. We have also made some study on a high resolution plate made specifically for mammography. The mammography images were performed on an ACR phantom, a CD MAM contrast detail phantom and CIRS detailed and curved phantoms. A 3M 18 x 24 cm Imaging Plate (IP) was used. The study was based on the comparison of 3M images and those taken from a screen-film system, and also the storage phosphor imaging plate taken from a Fuji 9000 computed radiography (CR) system. The evaluation of the system was divided into two categories: self evaluation (image evaluation based on the 3M plate itself) and comparison with the screen-film and Fuji 9000 CR systems. The categories for evaluation were based on the noise, contrast, sharpness, overall image quality, and overall diagnostic content. A scale of 1-5 was applied in which 1 was unacceptable performance and 5 was excellent performance. The comparisons of the results are listed in the appropriate tables.

2.1 Dosimetry

The exam rooms at Georgetown University Medical Center were again tested, using the dosimeter for consistency of x-ray exposure. The new sets of dosimetry were performed. The Radcal Model 9010MS Radiation Monitor with 90x5-6M and 90x5-180 ion chambers was used for dose measurement. The entrance dose was measured for the primary beam at the center of the phantoms. The results of exposure were consistent for different kVp and mAs.

2.2 Clinical Evaluation for Thin and Medium Sized Anatomy

After some experience with physics and anthropomorphic phantoms and optimizing the exposure technique the system was evaluated based on system performance in the clinical environment. During the phantom study the system was adjusted and recalibrated for better performance and for different generations of the plate. We believe that the 3M system is now ready for at least thin and medium size anatomy. In this phase the 3M system was evaluated based on different patients' anatomy such as:

- 1- Hand (PA)
- 2- Foot (AP)
- 3- Ankle (AP, Lateral)
- 4- Elbow (Lateral)
- 5- Knee (Lateral)
- 6- Shoulder (AP)

The study was performed using the standard exposure technique used at Georgetown University Medical Center (GUMC) for a range of kVp, mA, and exposure time, depending on the application of the individual anatomy. Source to Detector Distance (SDD) is fixed at 40 inches (102 cm). The exposures are fixed for screen-film and storage phosphor Fuji computed radiography (FCR) 9000 systems, but vary for the 3M system for preliminary image optimization. The standard techniques used for screen-film system are listed in Table I:

Table I. Standard Techniques For Different Anatomical Regions

Anatomy	kVp	mA	sec.	mAsec	SDD	Bucky	Tabletop	AFS(large)	AFS(small)
Hand (Ext. Cassette)	60	250	.02	5	40"		x		x
Foot (Ext. Cassette)	63	250	.02	5	40"		x		x
Foot (LAT) (Ext. Cassette)	63	250	.02	5	40"		x		x
Ankle (Ext. Cassette)	63	250	.02	5	40"		x		x
Knee	66	250	.025	6.3	40"	x		x	
Elbow	63	250	.025	6.3	40"		x		x
Shoulder	70	250	.04	10	40"	x			x

Note : STANDARD TECHNIQUE REFERS TO THE ONE USED IN SCREEN-FILM RADIOGRAPHY

SDD Source to Detector Distance

AFS Focal Spot Size

2.3 Patient Recruitment

Patients who are male or female coming into the main radiology department for routine exams will be asked to give written informed consent for one additional image on the 3M imaging plate. The original image will be on screen-film system or Fuji 9000 computed radiography (CR) system. The informed consent will be obtained by a member of the Georgetown University Hospital staff. The form will be kept at GUMC. The patient demographic information will be kept confidential from 3M personnel. The identification of each patient in the 3M database will be based on a three digit number and the first initial of the patient's first name and the first 3 letters of the patient's last name (e.g., KINR 001). The data collection form has information about demographic data, exam type, clinical information (exam, view, exposure technique, etc.), and signature section for Principal Investigator, and an RT's initial from both GUMC and 3M resident technical personnel.

3.0 RESULTS

After the data collection, the images are evaluated by our radiologist and the results are tabulated in appropriate appendices. In the third year of the study, we have carried out 18 patient exams for hand, foot, ankle, knee, elbow and shoulder. The Data Collection Form for patient study is listed in Appendix I. The number of patients in each category is listed in Table II. The 3M images were compared to 10 screen-film images and 8 FCR 9000 images. During that time the 3M system had some deficiency in image quality and we had to wait until the system was fixed, which delayed the whole process. The patients' ages ranged from 19 to 84 years old, and the sex coincidentally was distributed such that half of them were male and half female. For the comparison, ten images were made with screen-film system and eight images with FCR 9000. The clinical log of the patients are listed in Tables III and IV. The tables include enrollment number, date of exam, sex, age, exam, view, and exposure technique, along with the 3M plate ID number and read out voltage, as well as plate reader scanning criteria and the comparison with screen-film or storage phosphor FCR 9000 systems.

Table II. The Distribution of Patients in Selected Exams

Exam	No. of Exam
Hand	5
Foot	6
Elbow	1
Knee	1
Ankle	2
Shoulder	3

Table III. Patient Demographic Information and Exposure Technique

Enrollmen	Date	Sex	Age	Exam	View	kVp	mAs	Grid	Room
KINR 001	15-Sep-94	F	73	Hand	PA	60	5	N	10
CHUE 002	21-Sep-94	M	19	Foot	AP	63	6.3	N	10
MATR 003	21-Sep-94	M	71	Hand	PA	61.5	3.2	N	Gorman
BAZS 004	22-Sep-94	F	55	Foot	AP	63	5	N	Gorman
MCMM 005	26-Sep-94	F	55	Hand	PA	60	5	N	Gorman
HERJ 006	26-Sep-94	M	38	Ankle	Lateral	63	6.3	N	Gorman
GERL 007	29-Sep-94	F	42	Ankle	AP	60	5	N	Gorman
WDGD 008	29-Sep-94	M	57	Shoulder	AP	77	20	Y	16
STEJ 009	5-Oct-94	M	30	Elbow	Lateral	63	6.3	N	Gorman
MYLE 010	5-Oct-94	M	19	Foot	AP	63	5	N	Gorman
BARL 011	10-Oct-94	F	34	Hand	PA	60	5	N	Gorman
COOP 012	10-Oct-94	M	31	Hand	PA	60	5	N	Gorman
TYRS 013	12-Oct-94	F	46	Foot	AP	63	5	N	Gorman
DELJ 014	12-Oct-94	M	21	Foot	AP	63	5	N	10
HOLL 015	14-Oct-94	F	47	Foot	AP	66	6.3	N	Gorman
HARL 016	13-Apr-95	M	84	Shoulder	AP	70	20	Y	16
SUDA 017	13-Apr-95	F	45	Knee	Lateral	63	5	N	16
PEEM 018	14-Apr-95	F	40	Shoulder	AP	70	20	Y	16

Table IV. Plate Reader Information and Control Device

Enrollment	Date	Plate ID	Plate V(x)	Reading V(r)	Scan	Control
KINR 001	15-Sep-94	H0146	8	2.5	Hi Res	FCR HR-V
CHUE 002	21-Sep-94	H1024	8	3	Hi Res	FCR HR-V
MATR 003	21-Sep-94	H1024	8	3	Hi Res	SF System
BAZS 004	22-Sep-94	H1024	8	3	Hi Res	SF System
MCMM 005	26-Sep-94	H1024	8	3	Hi Res	SF System
HERJ 006	26-Sep-94	H1024	8	3	Hi Res	SF System
GERL 007	29-Sep-94	H1034	8	3	Hi Res	FCR HR-V
WDGD 008	29-Sep-94	H1024	8	3	Hi Res	SF System
STEJ 009	5-Oct-94	H1036	8	3	Hi Res	SF System
MYLE 010	5-Oct-94	H1034	8	3	Hi Res	SF System
BARL 011	10-Oct-94	H0146	8	3	Hi Res	SF System
COOP 012	10-Oct-94	H1034	8	3	Hi Res	SF System
TYRS 013	12-Oct-94	H1036	8	3	Hi Res	SF System
DELJ 014	12-Oct-94	H1146	8	3	Hi Res	FCR HR-V
HOLL 015	14-Oct-94	H1136	8	3	Hi Res	SF System
HARL 016	13-Apr-95	H1167	8	3	Hybrid	FCR HR-V
SUDA 017	13-Apr-95	H1148	8	3	Hybrid	FCR HR-V
PEEM 018	14-Apr-95	H1148	8	3	Hybrid	FCR HR-V

Note:

- FCR HR-V is related to Fuji Computed Radiography 9000 System with High Resolution Plate.
- SF System is Screen-Film System using Fuji HR-G 50 speed film system.

In order to evaluate the 3M imaging system in a clinical environment, the number of patients were selected based on thin and medium size anatomy. The system was evaluated for noise, contrast, sharpness, overall image quality, and overall diagnostic information. The evaluation was also based on two categories: self evaluation and comparison against two controls: one to screen-film (SF) system and the other to FCR 9000 system. Appendix I includes the self evaluation and comparison to control for each patient. The results of the self evaluation and comparison with SF and FCR 9000 systems are listed in Appendix II. For each patient, the self evaluation and the comparison with two controls have been combined as one sheet and listed in Appendix III.

4.0 DISCUSSIONS

A series of limited patient studies were performed on thin and medium sized anatomy. The focus was on the extremities (hand, foot) and the shoulder in order to determine the 3M system performance in the clinical environment for mammography. The optimized (accepted image) images from conventional screen-film (SF) system were compared with the 3M images. Image processing was performed on the 3M images in order to find the preliminary optimum image for comparison with SF images. The images were compared to those taken from SF images and evaluated for clinical studies. The evaluation was performed in the following two ways:

4.1 3M Self Evaluation

The 3M images were self evaluated based on five categories: noise, contrast, sharpness, overall image quality, and overall diagnostic information. The rating was between 1 (unacceptable) to 5 (excellent). Appendix II lists the self evaluation of the 3M system.

Noise

The noise was the most important problem of the 3M system. Through different generations of the imaging plate, the noise was reduced. The images are rated from unacceptable to marginal and in a few, foot exams are considered good.

Contrast

The contrast also varied from marginal to very good in rating. Most medium size anatomy has marginal contrast whereas hand and foot images have good or very good contrast.

Sharpness

The system resolution is rated as good to very good and in a few cases even excellent. Only in one case the system did not perform well.

Overall Image Quality

The overall system image quality varies between marginal to very good in rating. Most of our hand and foot images are showing very good image quality.

Overall Diagnostic Content

The overall diagnostic information are rated from marginal to excellent. In two cases such as hand (PA) and shoulder (AP) the rating was unacceptable. Most of the exam ratings are good or better.

4.2 3M Versus Control

The 3M images were compared to those images taken from two modalities: one screen-film system and the other FCR 9000 system. The comparison was similar to the self evaluation and was based on five categories: noise, contrast, sharpness, overall image quality, and overall diagnostic information. The rating was between 1 (Strong Control Preference) to 5 (Strong 3M Preference). Appendix III lists the comparison between 3M images and screen-film and FCR 9000 images. Ten of the control images were SF and eight of them were CR images.

Noise

3M images were compared to SF and FCR 9000 images. In terms of noises, SF images are only slightly better over than the 3M images, whereas FCR images in most cases are strong preferred to the 3M images. In one of the shoulder studies there was no preference between 3M and FCR images.

Contrast

The contrast also varies from mild control preference in 6 cases to mild 3M preference in 6 cases. In some of the exams such as ankle, knee, and hand, the contrast of the 3M images and control images are similar/equal. In one shoulder study, the FCR image is better than the 3M image.

Sharpness

In the self evaluation rating, the 3M system has better resolution than both control systems. In 11 cases 3M images have a slight advantage over the two control system images and in 2 cases the 3M images have a stronger advantage over SF and FCR images.

Overall Image Quality

The overall system image quality varies between mild control preference to no preference and in some cases to 3M mild preference.

Overall Diagnostic Content

The rating for the overall diagnostic information of the 3M system varies between mild control preference to mild 3M preference. In cases such as ankle (SF) and shoulder (FCR) exams the control has a strong performance than the 3M system.

5.0 CONCLUSIONS

In the evaluation of the 3M digital mammography based on micro-lithography, the feasibility of the system was studied. The focus was on the imaging of body parts (e.g., extremities) less radio-sensitive than the breast. A series of exams were performed on the hand, foot, ankle, elbow, knee and shoulder in order to evaluate the 3M digital radiography system's performance under the standard technique(s). The optimized base line (accepted image) images are those taken from the conventional screen-film (SF) system and the Fuji 9000 storage phosphor (SP) based computed radiography system. Image processing was performed on the 3M images as little as possible in order to find the optimum images for comparison with SF and SP images. KHOROS, the image processing software developed by the University of New Mexico, was used for this study.

Noise reduction was achieved for most exams through image processing. In some of our studies the elimination of complete noise also eliminated the fine structure of the image. We

observed that the noise is more visible on the darker side of the image. Limited image processing and elimination of pattern noise will produce better image quality.

During the study period several imaging plates were made by acquiring different plate structures in order to study the performance of the 3M digital radiography system. Each generation performed better than the previous one in terms of noise reduction.

In the final phase of the 3M digital radiography system study and after a series of extensive experiments, we came to the following conclusions and recommendations:

- 1- The 3M system has shown for some cases the capability of operating in the lower kVp with lower exposure dose as compared to the screen-film system with as little image processing as possible to enhance the images.
- 2- The variation of mA in the applicable range of radiography has little effect on the images for foot and hand.
- 3- Noise should be reduced in order to get better image quality. This was shown in our last few clinical studies when a new plate was manufactured. In those studies, because of the new plate's structure, very little image processing was used to enhance the images. This issue should be carefully studied.
- 4- The standard exposure technique system is capable of producing better images for thin parts of the anatomy than for the thick parts. In order to achieve better resolution and better contrast for thick body parts, the 3M system needs to operate at a higher exposure dose than the conventional technique. Hopefully the dose can be reduced through mathematical image optimization and image processing.
- 5- We still need to determine what or how much will be gained from image processing.
- 6- What are the characteristics of the noise? (Shape, pattern, etc.). The types of noise influencing images can result from quantum noise (x-ray quantum noise and light photon noise) and fixed noise (imaging plate structure noise, electrical system noise, quantization noise, and other noise). This should be addressed if future study is needed. Some of the fixed noise can be reduced as the new generation of the imaging plate is manufactured. The noise reduction improvement was seen when the latest generation of the imaging plate was used.

The overall conclusions based on patient study and comparison with SF and FCR 9000 systems are as follows:

- 7- In most of our patient studies the image noise reduction is the most important factor that gives SF and FCR 9000 systems advantages over the 3M system.
- 8- The contrast in some of 3M images is better than that of the SF images, but not as good as the FCR 9000 images.
- 9- In most cases, 3M system resolution is better than SF and FCR 9000 systems.

- 10-** In most cases there is no preference of overall image quality are between the 3M system and the other two modalities.
- 11-** The overall diagnostic content does not differ significantly among the 3M and other systems.
- 12-** In terms of overall system performance, with the exception of noise, the 3M system has better performance compared to the screen-film system, but not as good as the FCR 9000 system.
- 13-** The image quality for mammography phantoms (e.g., CIRS, CD MAM, and ACR) are not good in comparison to screen-film mammography system. 3M images are noisy in mammography energy range. The images also do not have enough contrast.
- 14-** The final conclusion is that, the 3M system is not suitable at this time to conduct clinical trial for mammography. The system is noisy and does not have enough contrast to go to mammography energy range. In order to get reasonable image quality, we have to increase the dose level which will not be acceptable in clinical settings.

6. REFERENCES

1. "Breast cancer: Cancer Facts and Figures," American Cancer Society, 1995.
2. E. Silverberg, and J.A. Lubera, "Cancer Statistics," CA-A Cancer Journal for Clinicians, 83:5, 1988.
3. J.A. Peter Pare, and R.G. Fraser, "Synopsis of Disease of the Chest," W.B. Saunders Company, Philadelphia, 1983.
4. D.B. Kopans, "Breast Imaging," J.B. Lippincott Company, Philadelphia, 1989.
5. Daniel Kopans and Donald Plewes, "Digital Mammography", Presented at the National Cancer Institute Consensus Conference "Breast Imaging; State-of-the-Art and Technologies for the Future", September 4-6, 1991.
6. Andrew D.A. Maidment, Rebecca Fahrig, and Martin J. Yaffee, "Dynamic Range Requirements in Digital Mammography," Med. Phys. **20**, 1621-1633 (1993).
7. Robert F. Wagner, "Low Contrast Sensitivity of Radiologic, CT, Nuclear Medicine, and Ultrasound Medical Imaging Systems," IEEE Trans. on Med. Imaging **MI-2**, 105-121 (1983).
8. John M. Sabol, Ian C. Soutar, and Donald B. Plewes, Observer Performance and Dose Efficiency of Mammographic Scanning Equalization Radiography," Med. Phys. **20**, 1517-1525 (1993).
9. Hunter, T.B., and Fajardo, L.L., "Digital Genitourinary, Gastrointestinal, and Breast Radiology," in Digital Imaging in Diagnostic Radiology, Newell and Kelsey eds., Churchill Livingstone, New York (1990).

10. Chan, H.P., Vyborny, C.J., MacMahon, H., et al., "Digital mammography: ROC studies of the effect of pixel size and unsharp-mask filtering on the detection of subtle microcalcifications," in *Invest Radiol*, 22:581, (1987).
11. Oestmann, J.W., Kopans D., Hall, D.A., et al., "A comparison of digitized storage phosphors and conventional mammography in the detection of malignant microcalcifications," in *Invest Radiol*, 23:725, (1988).
12. Johns, P.C., Yaffe, M.J., "X-ray characterization of normal and neoplastic breast tissues," *Med. Phys.* 12(1), 32-39, (1985).
13. Korn et. al. US Patent 4,176,275; Nov 27, 1978.
14. Korn, D.M., Johnson, S.P., Nelson, O.L., and Ziegler, R.J.: A method of electronic readout of electrophotographic and electroradiographic images. *Journal of Applied Photographic Engineering* 4(4): 178-182.

APPENDIX I

3M Digital Radiography Evaluation Form For Self Evaluation and Versus Control Systems

3M Digital Radiography Evaluation

Patient ID: KINR 001

Exam/View: HAND / PA

Control: ☒ FCR 9000 ☐ Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: CHUE 002

Exam/View: FOOT / AP

Control: FCR 9000 Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: MATR 003

Exam/View: HAND / PA

Control: FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: BAZS 004

Exam/View: FOOT / AP

Control: ☐ FCR 9000 ☐ Screen-Film ☐

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: MCMM 005

Exam/View: HAND / PA

Control: ☐ FCR 9000

☒ Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: HERJ 006

Exam/View: ANKLE / LATERAL

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: GERL 007

Exam/View: ANKLE / AP

Control: FCR 9000 Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: EDGD 008

Exam/View: SHOULDER / AP

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: STEJ 009

Exam/View: ELBOW / LATERAL

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: MYLE 010

Exam/View: FOOT / AP

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: BARL 011

Exam/View: HAND / PA

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: COOP 012

Exam/View: HAND / PA

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: TYRS 013

Exam/View: FOOT / AP

Control: FCR 9000 Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: DELJ 014

Exam/View: FOOT / AP

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: HOLL 015

Exam/View: FOOT / AP

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: HARL 016

Exam/View: SHOULDER / AP

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: SUDA 017

Exam/View: KNEE / LATERAL

Control:

FCR 9000

Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Digital Radiography Evaluation

Patient ID: PEEM 018

Exam/View: SHOULDER / AP

Control: FCR 9000 Screen-Film

Self Evaluation

	Unacceptable	Marginal	Good	Very good	Excellent
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

3M Versus Control

	Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
Noise	1	2	3	4	5
Contrast	1	2	3	4	5
Sharpness	1	2	3	4	5
Overall Image Quality	1	2	3	4	5
Overall Diagnostic Content	1	2	3	4	5

APPENDIX II

3M Self Evaluation

Based on

**Noise, Contrast, Sharpness, Overall Image Quality, and
Overall Diagnostic Content**

3M Digital Radiography Evaluation

Self Evaluation for Noise

Patient ID	Date	Sex	Age	Exam	View	Unacceptable	Marginal	Good	Very good	Excellent
KINR 001	15-Sep-94	F	73	Hand	PA	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	1	2	3	4	5

3M Digital Radiography Evaluation

Self Evaluation for Contrast

Patient ID	Date	Sex	Age	Exam	View	Unacceptable	Marginal	Good	Very good	Excellent
KINR 001	15-Sep-94	F	73	Hand	PA	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	1	2	3	4	5

3M Digital Radiography Evaluation

Self Evaluation for Sharpness

Patient ID	Date	Sex	Age	Exam	View	Unacceptable	Marginal	Good	Very good	Excellent
KINR 001	15-Sep-94	F	73	Hand	PA	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	1	2	3	4	5

3M Digital Radiography Evaluation

Self Evaluation for Overall Image Quality

Patient ID	Date	Sex	Age	Exam	View	Unacceptable	Marginal	Good	Very good	Excellent
KINR 001	15-Sep-94	F	73	Hand	PA	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	1	2	3	4	5

3M Digital Radiography Evaluation

Self Evaluation for Overall Diagnostic Content

Patient ID	Date	Sex	Age	Exam	View	Unacceptable	Marginal	Good	Very good	Excellent
KINR 001	15-Sep-94	F	73	Hand	PA	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	1	2	3	4	5

APPENDIX III

Comparison Between 3M Images and Screen-Film Images and Fuji 9000 Computed Radiography Images

Based on

**Noise, Contrast, Sharpness, Overall Image Quality, and
Overall Diagnostic Content**

3M Digital Radiography Evaluation

3M Versus Control for Noise

Patient ID	Date	Sex	Age	Exam	View	Control		Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
KINR 001	15-Sep-94	F	73	Hand	PA	FCR	SF	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	FCR	SF	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	FCR	SF	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	FCR	SF	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	FCR	SF	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	FCR	SF	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	FCR	SF	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	FCR	SF	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	FCR	SF	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	FCR	SF	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	FCR	SF	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	FCR	SF	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	FCR	SF	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	FCR	SF	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	FCR	SF	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	FCR	SF	1	2	3	4	5

3M Digital Radiography Evaluation

3M Versus Control for Contrast

Patient ID	Date	Sex	Age	Exam	View	Control		Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
KINR 001	15-Sep-94	F	73	Hand	PA	FCR	SF	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	FCR	SF	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	FCR	SF	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	FCR	SF	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	FCR	SF	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	FCR	SF	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	FCR	SF	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	FCR	SF	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	FCR	SF	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	FCR	SF	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	FCR	SF	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	FCR	SF	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	FCR	SF	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	FCR	SF	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	FCR	SF	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	FCR	SF	1	2	3	4	5

3M Digital Radiography Evaluation

3M Versus Control for Sharpness

Patient ID	Date	Sex	Age	Exam	View	Control		Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
KINR 001	15-Sep-94	F	73	Hand	PA	FCR	SF	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	FCR	SF	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	FCR	SF	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	FCR	SF	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	FCR	SF	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	FCR	SF	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	FCR	SF	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	FCR	SF	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	FCR	SF	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	FCR	SF	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	FCR	SF	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	FCR	SF	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	FCR	SF	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	FCR	SF	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	FCR	SF	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	FCR	SF	1	2	3	4	5

3M Digital Radiography Evaluation

3M Versus Control for Overall Image Quality

Patient ID	Date	Sex	Age	Exam	View	Control		Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
KINR 001	15-Sep-94	F	73	Hand	PA	FCR	SF	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	FCR	SF	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	FCR	SF	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	FCR	SF	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	FCR	SF	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	FCR	SF	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	FCR	SF	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	FCR	SF	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	FCR	SF	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	FCR	SF	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	FCR	SF	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	FCR	SF	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	FCR	SF	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	FCR	SF	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	FCR	SF	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	FCR	SF	1	2	3	4	5

3M Digital Radiography Evaluation

3M Versus Control for Overall Diagnostic Content

Patient ID	Date	Sex	Age	Exam	View	Control		Strong Control Preference	Mild Control Preference	No Preference	Mild 3M Preference	Strong 3M Preference
KINR 001	15-Sep-94	F	73	Hand	PA	FCR	SF	1	2	3	4	5
CHUE 002	21-Sep-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
MATR 003	21-Sep-94	M	71	Hand	PA	FCR	SF	1	2	3	4	5
BAZS 004	22-Sep-94	F	55	Foot	AP	FCR	SF	1	2	3	4	5
MCMM 005	26-Sep-94	F	55	Hand	PA	FCR	SF	1	2	3	4	5
HERJ 006	26-Sep-94	M	38	Ankle	LA	FCR	SF	1	2	3	4	5
GERL 007	29-Sep-94	F	42	Ankle	AP	FCR	SF	1	2	3	4	5
EDGD 008	29-Sep-94	M	57	Shoulder	AP	FCR	SF	1	2	3	4	5
STEJ 009	5-Oct-94	M	30	Elbow	LA	FCR	SF	1	2	3	4	5
MYLE 010	5-Oct-94	M	19	Foot	AP	FCR	SF	1	2	3	4	5
BARL 011	10-Oct-94	F	34	Hand	PA	FCR	SF	1	2	3	4	5
COOP 012	10-Oct-94	M	31	Hand	PA	FCR	SF	1	2	3	4	5
TYRS 013	12-Oct-94	F	46	Foot	AP	FCR	SF	1	2	3	4	5
DELJ 014	12-Oct-94	M	21	Foot	AP	FCR	SF	1	2	3	4	5
HOLL 015	14-Oct-94	F	47	Foot	AP	FCR	SF	1	2	3	4	5
HARL 016	13-Apr-95	M	84	Shoulder	AP	FCR	SF	1	2	3	4	5
SUDA 017	13-Apr-95	F	45	Knee	LA	FCR	SF	1	2	3	4	5
PEEM 018	14-Apr-95	F	40	Shoulder	AP	FCR	SF	1	2	3	4	5